

Rec'd PCT/PTO 01 FEB 2005



PCT/GB2003/003348

10/523023

INVESTOR IN PEOPLE

**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR
(b)

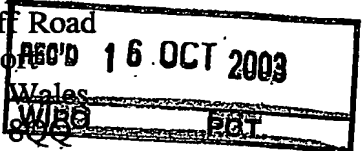
The Patent Office
Concept House

Cardiff Road

Newport

South Wales

NP10 8YQ



I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

M. Jenkins

Dated

26 September 2003

Best Available Copy

An Executive Agency of the Department of Trade and Industry

Patents Form 1/77

Patents Act 1977
(Rule 16)

THE PATENT OFFICE

- 2 AUG 2002

RECEIVED BY FAX

The
Patent
Office02AUG02 E738 9-1 C45839
P01/7700 0.00 0217996.8

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference

P1619

2. Patent application number

(The Patent Office will fill in this part)

0217996.8

02 AUG 2002

3. Full name, address and postcode of the or of each applicant (underline all surnames)

NOVAMEDIX DISTRIBUTION LTD
Julia House
3 Thermistocles Dervis Street
PO Box 3589, CY-1685
Nicosia, Cyprus

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

CYPRUS

7436249000

4. Title of the invention

AN INFLATABLE DEVICE FOR USE IN IMPULSE THERAPY

5. Name of your agent (if you have one)

MACLEOD ALLSOP

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Bledington Grounds
Bledington
Gloucestershire
OX7 6XL
G B

Patents ADP number (if you know it)

7454481000

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or

c) any named applicant is a corporate body.

See note (d)

Patents Form 1/77

0043402 02 AUG 02 04:46

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description

8

Claim(s)

3

Abstract

Drawing(s)

6

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

J R Allsop

Date

.08.02

12. Name and daytime telephone number of person to contact in the United Kingdom

J R Allsop

01608 659836

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

Patents Form 1/77

AN INFLATABLE DEVICE FOR USE IN IMPULSE THERAPY

FIELD OF THE INVENTION

The present invention relates to a device for use in intermittent impulse therapy,
5 particularly but not exclusively for applying intermittent impulse pressure to a human foot to enhance blood circulation around the body.

BACKGROUND OF THE INVENTION

The use of an inflatable garment applied to a limb or other area of the human body
10 as a means of enhancing blood circulation is a well established medical technique with proven clinical benefits.

Such a device, known as the A-V Impulse System[®] is in widespread use and is designed to apply intermittent impulses to the foot in such a manner as to mimic
15 ambulatory movement which is known periodically to empty the veins of the foot to drive the blood throughout the body.

The A-V Impulse System[®] comprises an inflatable bladder being part of or integral with means in the form of a foot wrap for securing the bladder in the plantar arch of
20 the foot and about the area to be treated.

During use the bladder is filled with a fluid such as air to expand and apply cyclical force to the plantar arch directed in such a way as to empty the plantar veins of the foot.

The bladder is held pressurised for a period before releasing the fluid and then the cycle is repeated.

The rate of filling or venting of the bladder may vary from fractions of a second to several seconds according to application, but is dependent upon the bladder volume, fluid flow rate and operating pressure.

To be effective the bladder has to be filled rapidly and the consequent high velocity flow of fluid results in the generation of noise as the fluid passes from the controlling system through the connecting tubing into the bladder.

Noise reduction may be achieved by reducing the fluid flow rate but this is not a feasible remedy because it affects the required rate of pressurisation and desired operating characteristics.

SUMMARY OF THE INVENTION

It is an object of the present invention to overcome the disadvantages of the prior art by providing the inflatable bladder with an internal volume reducing media or component providing means whereby the same bladder pressurisation is achievable with a lower rate of fluid flow compared with the prior art. A lower rate of fluid flow means lower fluid usage and a reduction in the generation of noise which occurs

when the bladder is being filled. Thus patient comfort is increased while maintaining the effectiveness of the therapy treatment.

According to the present invention there is provided a device for use in applying
5 Impulse therapy to a limb of the human body comprising an inflatable bladder,
means for providing intermittent pulses of fluid to the bladder in accordance with a
pre-determined timed sequence of pressure hold and pressure release, means for
securing the bladder around the limb of the human body to apply the bladder to the
area to be treated, characterised in that the bladder is provided with a volume
10 reducing internal component which acts to dissipate the flow of fluid into the
bladder with accompanying reduction in fluid flow rates and noise generated by the
fluid flow during pressurisation of the bladder.

Preferably the internal media is of foam material which may be attached to internal
15 walls of the bladder or fitted loosely within the bladder without attachment.

It may be advantageous to provide the foam with channels for movement of
pressurised air within the bladder.

20 Other features and advantages will now be described with reference to a set of
accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described by way of example with reference to the accompanying drawings wherein:

- 5 Figures 1 and 2 show, in plan and cross-sectional view respectively, a device for applying impulse therapy to a human foot;

Figures 3 and 4 show respectively a side and front view of the device of Figures 1 and 2 as applied to a human foot;

10

Figures 5 and 6 show in plan and cross-sectional view respectively, a device for impulse therapy of the human foot in accordance with the invention;

- 15 Figures 7 and 8 show the a side and front view respectively of the device of Figures 5 and 6 applied to a human foot;

Figure 9 shows the device of Figure 5 and 6 with part of the outer covering cut away to show the internal media of the bladder of the device;

- 20 Figure 10 shows a plan view of the device of Figures 5 and 6 with part of the outer covering of the device cut away to reveal the internal media of the bladder partly-filled by an amount sufficient to occupy the plantar arch of the human foot;

Figure 11 is a cross-sectional view of the device of Figure 9;

25

5

Figure 12 is a cross-sectional view through the internal media within the bladder of the device of Figure 10 illustrating a preferential profile of the internal media designed to occupy the plantar arch of the foot; and

- 5 Figure 13 shows a plan view of the device in accordance with the invention with part of the outer covering of the device cut away to reveal the internal media of the bladder provided with air flow channels cut into the media.

10 BEST MODES OF CARRYING OUT THE INVENTION

A device for intermittent impulse therapy to be applied to the human foot is shown in Figures 1, 2, 3 and 4 in accordance with the prior art.

- 15 The device comprises an inflatable bladder or pad formed from two films 1, 2 of flexible polymeric material joined at the periphery 3 by, for example, radio frequency (RF) welding to form an essentially sealed pressure vessel or bladder 4.

- The bladder 4 is formed integral with a foot wrap 5, see Figure 3, which can be secured, as by velcro action, around the foot 6 as shown in Figures 3 and 4 to hold
20 the bladder 4 generally within the plantar arch 7 of the foot 6 with a void 4 between the bladder 4 and foot arch.

- A port connection 8 is sealed to one of the films 1, 2 of the bladder 4 with a connection tube 9 attached to the port 8 to allow air to be admitted and vented
25 from the bladder 4.

6

As pressurised air is fed to the bladder 4, the bladder 4 is free to expand particularly into the arch 7 of the foot 6 and elsewhere over the bladder surface area, being constrained only by the foot itself and by resistance to outward expansion of the wrap 5 to which the bladder is attached.

During inflation of the bladder 4 air flows through the port connection 8 at high velocity which generates excessive noise caused by the geometry within the flow path of the air and by pressurised air impinging directly on to the inner wall 5 of the bladder 4 opposite the port connections 8.

It is to the elimination of the excessive noise caused by the movement of pressurised air as described that the present invention is directed and in this way to improve the performance of the impulse therapy device and enhance patient fit up, comfort and well-being.

The improved impulse therapy device in accordance with the invention is illustrated in Figures 5 through 13.

In these embodiments the device itself is constructed in accordance with the prior art as discussed with reference to Figures 1 through 4 with the exception that in accordance with the invention the bladder 4 is provided with an internal media 10 in the form preferably of a foam, gel or fluid reservoir which reduces the internal volume of the bladder. The internal media in accordance with the invention may be

attached to one or other, or both, films of the bladder 4. Alternatively, it may be freely inserted within the bladder 4.

The internal media acts to dissipate the flow of fluid within the bladder thus
5 reducing noise and also the amount of fluid necessary to achieve the required rate of pressurisation.

The improved bladder 4 of the impulse therapy device in accordance with the invention may be constructed by forming the internal media 10 by an injection
10 moulding process, either applied to bladders formed in accordance with the prior art or as part of multi-shot process to manufacture a bladder with an internal media by automated means, using for example a thermoplastic elastomer polymer together with a foaming technique to produce an integral cellular construction as the internal media.

15

The improved impulse therapy device in accordance with Figures 5 and 6 is shown applied to a human foot in Figures 7 and 8 in like manner as with the conventional impulse therapy device illustrated in Figures 3 and 4.

20 Whereas in the Figure 5 embodiment the media 10 fills the entire space within the bladder 4 in alternative form the media may be appropriately profiled 10' within the bladder such that when the device is applied to the foot the media conforms to the plantar arch 7, as illustrated with reference to Figures 10, 11 and 12.

The internal media 10 may be constructed from either a closed cell or open cell form according to the desired benefits of internal bladder volume reduction consistent with suitable air flow either immediately through and within the media, with channels 11 formed or cut into the media as shown in Figure 13 or over and
5 around the media.

The inclusion of an internal media within the bladder of the impulse therapy device as described above and in accordance with the invention, has significant actual and perceived implications for user comfort leading to improved product acceptance,
10 compliance and clinical results.

In addition, a specific improvement has been observed when using the improved impulse therapy device in accordance with the invention fitted more loosely than is recommended with the prior art device as described with reference to Figures 1
15 through 4. Without inclusion of the internal media within the bladder it is necessary to fit the garment to the foot relatively snugly to avoid over-inflation and thus excessive air consumption. A disadvantage of such a fit-up is to cause a static force to be applied to the limb throughout the uninflated phase of applied impulse pressure thereby to some extent hindering re-priming of the veins of the foot
20 following evacuation.

With the inclusion of the internal media the necessity to tighten the device as snugly as previously is reduced and consequently the static force on the foot is lessened allowing superior re-priming of the veins of the foot to occur.

25

CLAIMS

1. A device for use in applying Impulse therapy to a limb of the human body comprising an Inflatable bladder, means for providing intermittent pulses of fluid to the bladder in accordance with a pre-determined timed sequence of pressure hold and pressure release, means for securing the bladder around the limb of the human body to apply the bladder to the area to be treated, characterised in that the bladder is provided with a volume-reducing internal component which acts to dissipate the flow of fluid into the bladder with accompanying reduction in fluid flow rates and noise generated by the fluid flow during pressurisation of the bladder.
2. A device as claimed in Claim 1 wherein the internal component is of foam material.
3. A device as claimed in Claim 1 wherein the internal component is a gel.
4. A device as claimed in Claim 1 where in the internal component is a fluid reservoir.
5. A device as claimed in Claim 2 wherein the foam is attached to one or both walls of the bladder.
6. A device as claimed in Claim 5 wherein the foam is provided with air flow channels.

7. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an inflatable interior, means for providing intermittent impulses of fluid to the inflatable interior in accordance with a predetermined timed sequence of pressure hold and pressure release,
- 5 means for securing the flexible member around the limb of the human body to apply the member to the area to be treated, characterised in that the inflatable interior is filled or partially filled with a cellular component providing means for reducing fluid flow rates and noise during pulsed pressurisation of said inflatable interior of the flexible member.
- 10
8. A device as claimed in claim 7 wherein the cellular component acting as a sound absorbing media, is formed during construction of the bladder by an injection moulding process.
- 15 9. A device as claimed in claim 7 when the cellular component is a foam material.
10. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an inflatable chamber, means for providing
- 20 intermittent pulses of fluid to the inflatable chamber in accordance with a predetermined timed sequence of pressure hold and pressure release, means for securing the flexible member around the limb of the human body to apply the flexible member to the area to be treated, characterised in that the inflatable chamber is provided with means for varying the internal

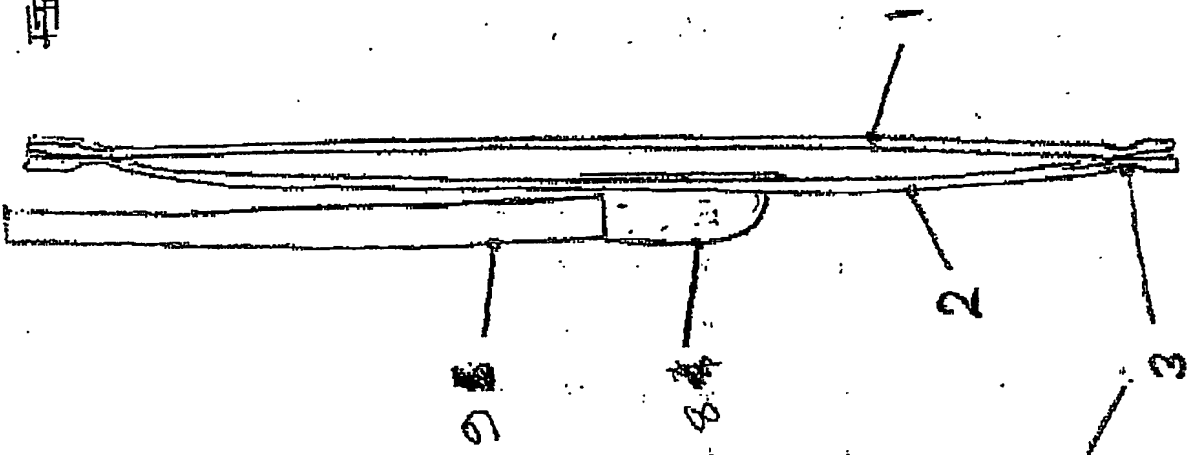
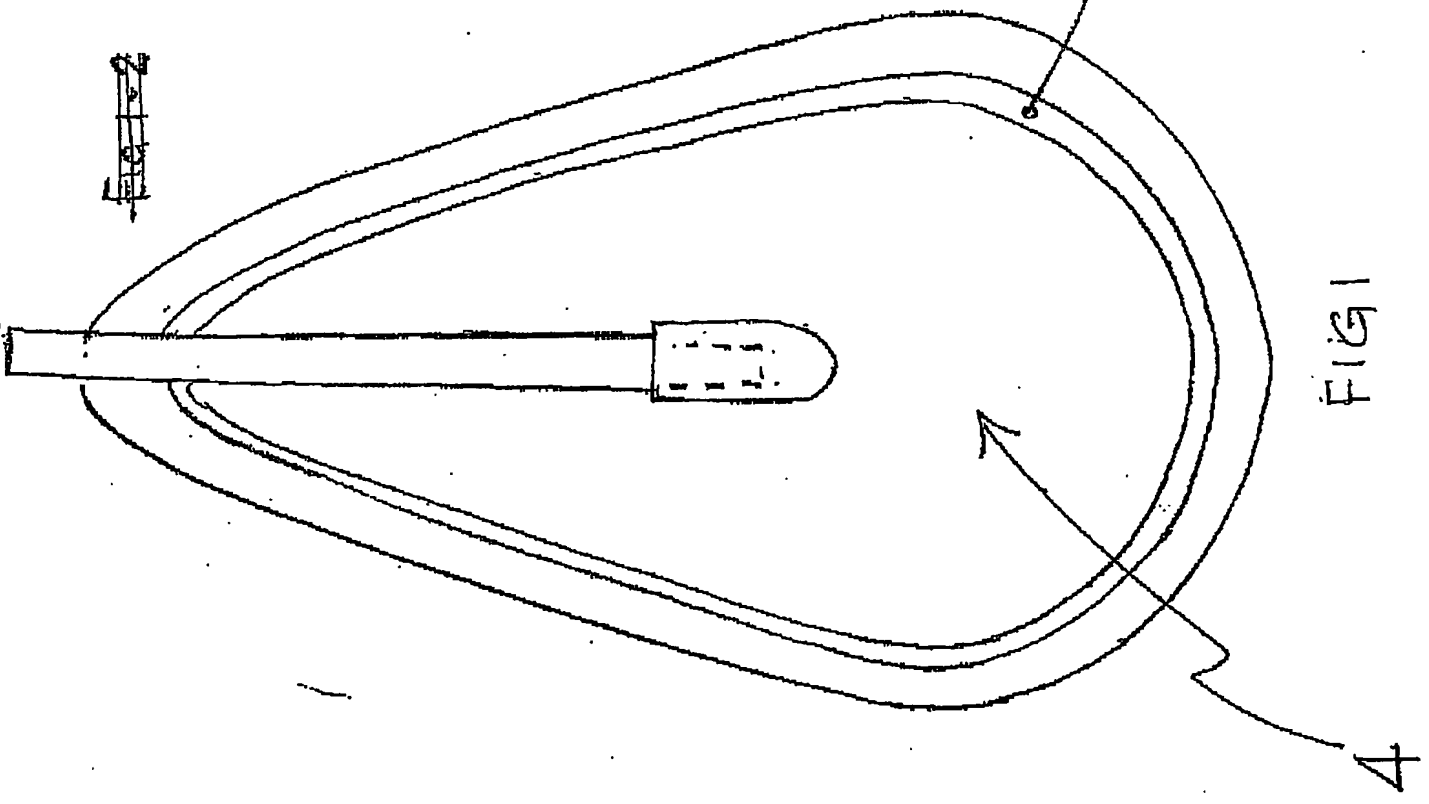
volume of the chamber thereby to control fluid flow rates and generation of noise during pressurisation of the chamber.

- 5 11. A device as claimed in claim 10 wherein said means for varying the internal volume of the chamber is a gel or liquid.
- 10 12. A device for use in applying impulse therapy to a limb of the human body comprising a flexible pad having an internal chamber adapted to inflate when supplied with fluid at a predetermined pressure, adjustable securing means for securing the pad around the limb of a human body at an adjustable pressure to apply the inflatable chamber to the area to be treated, and means within the chamber adapted to maintain the required pressurisation of the chamber with reduced rates of fluid flow and applied adjustable pressure of the pad against the limb by said securing means.
- 15

© Novamedix
1.5.02

CONFIGURATION OF
TYPICAL STANDARD BLADES

1/6



1/6

1/6

2/6

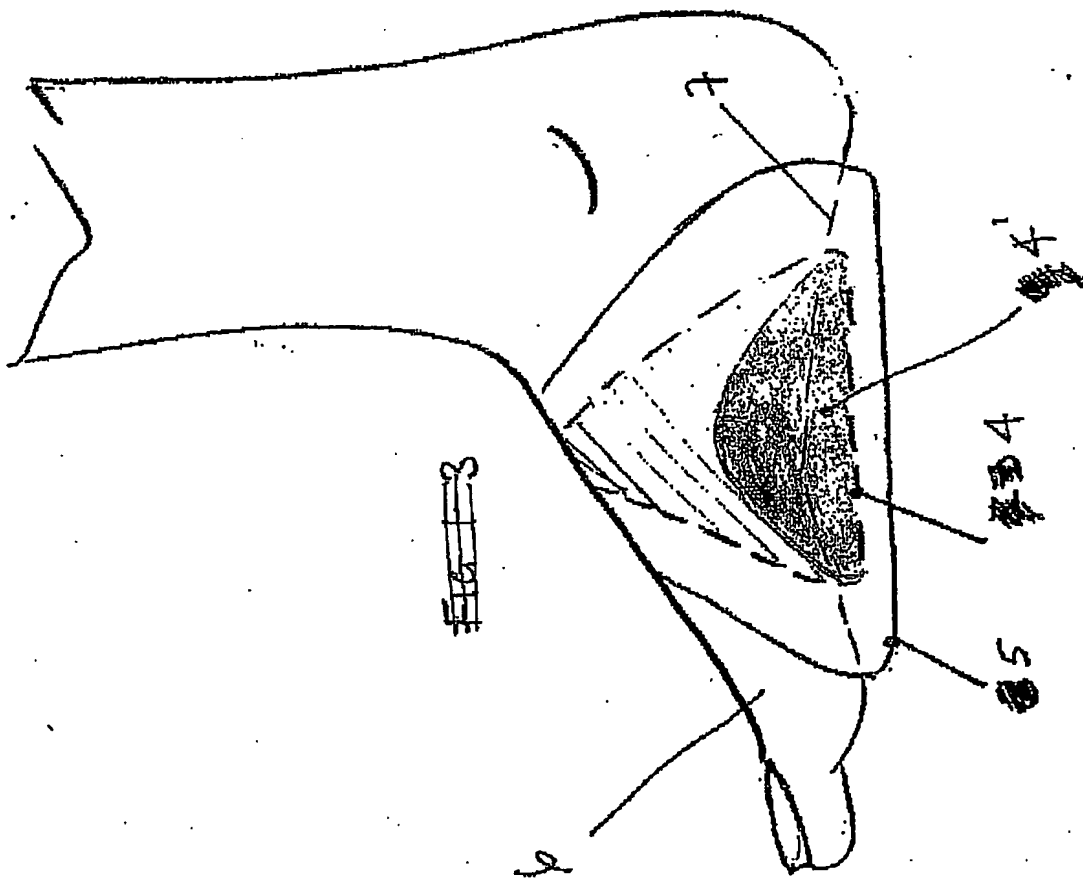


FIG 3

4
VOID BETWEEN BLADDER &
FOOT ARCH.

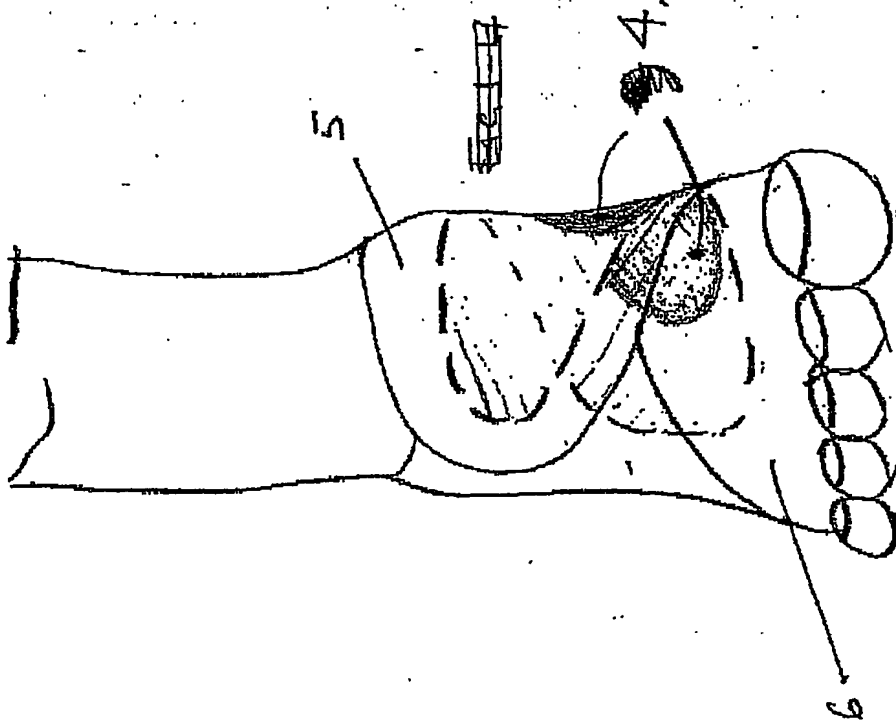
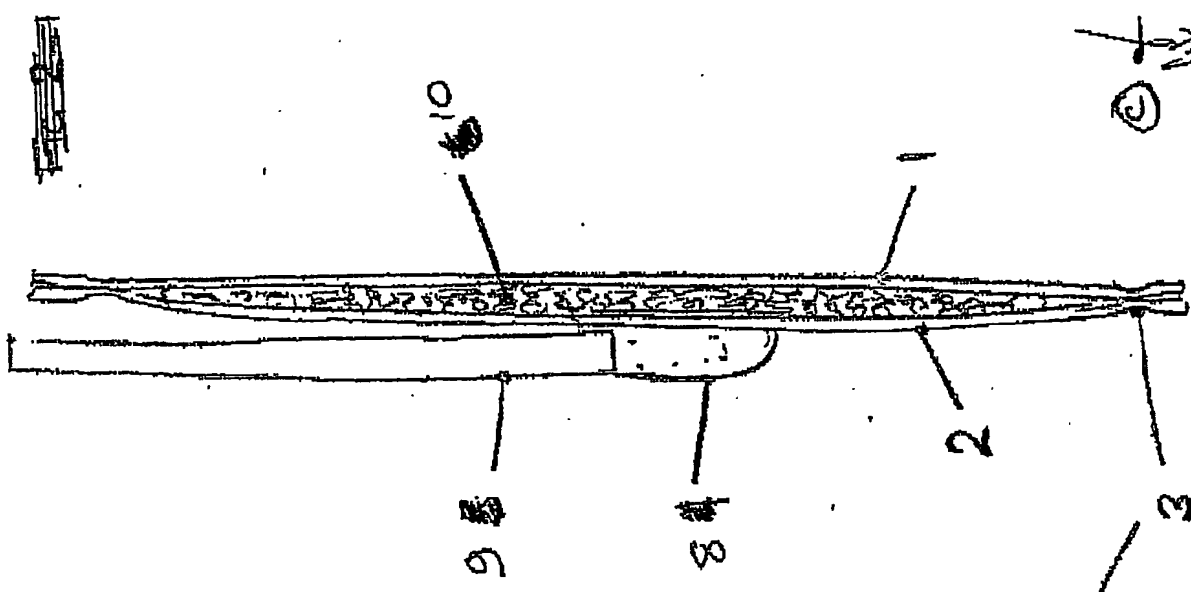
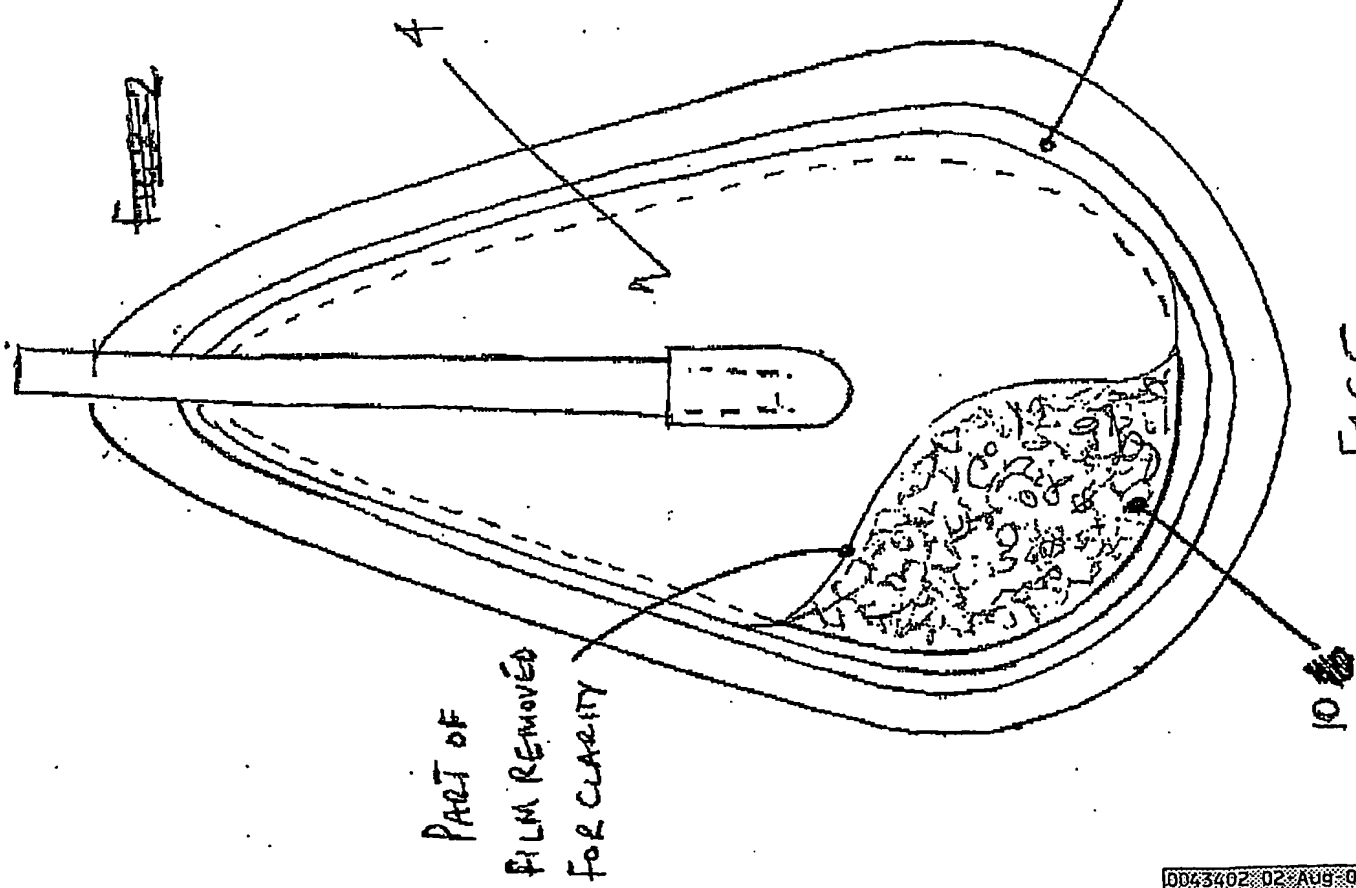


FIG 4

2 of Noramodys
1.502

~~FRONT & SIDE ELEVATIONS~~
~~OF FOOT SHOWING~~
~~BLADDER & PART OF GARGANTE~~

3/6



© Novamedix
11.5.02

FIG 6- CONFIGURATION OF
TYPICAL IMPROVED BLADDER

4/6

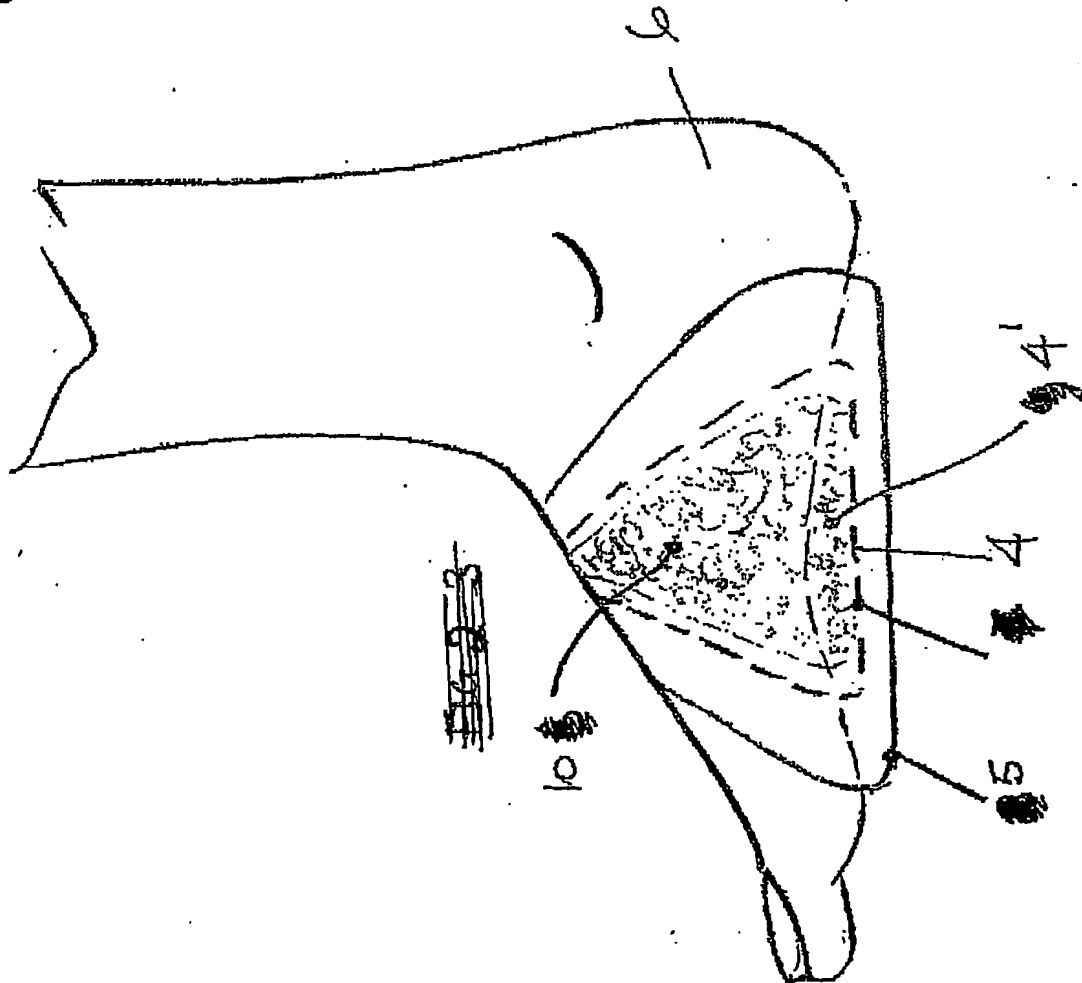


FIG 7
4' VOID BETWEEN BLADDER & FOOT ARCH.

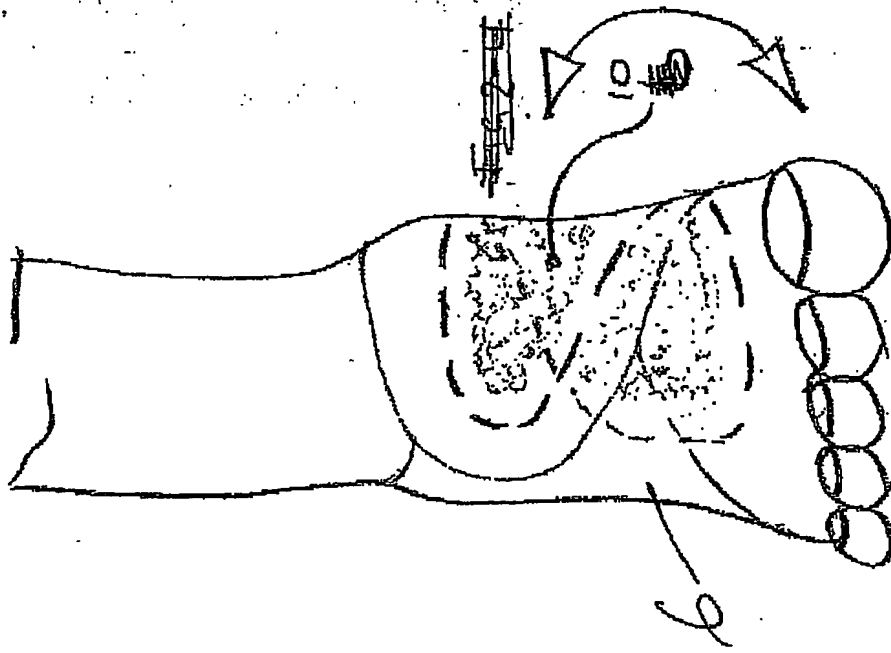


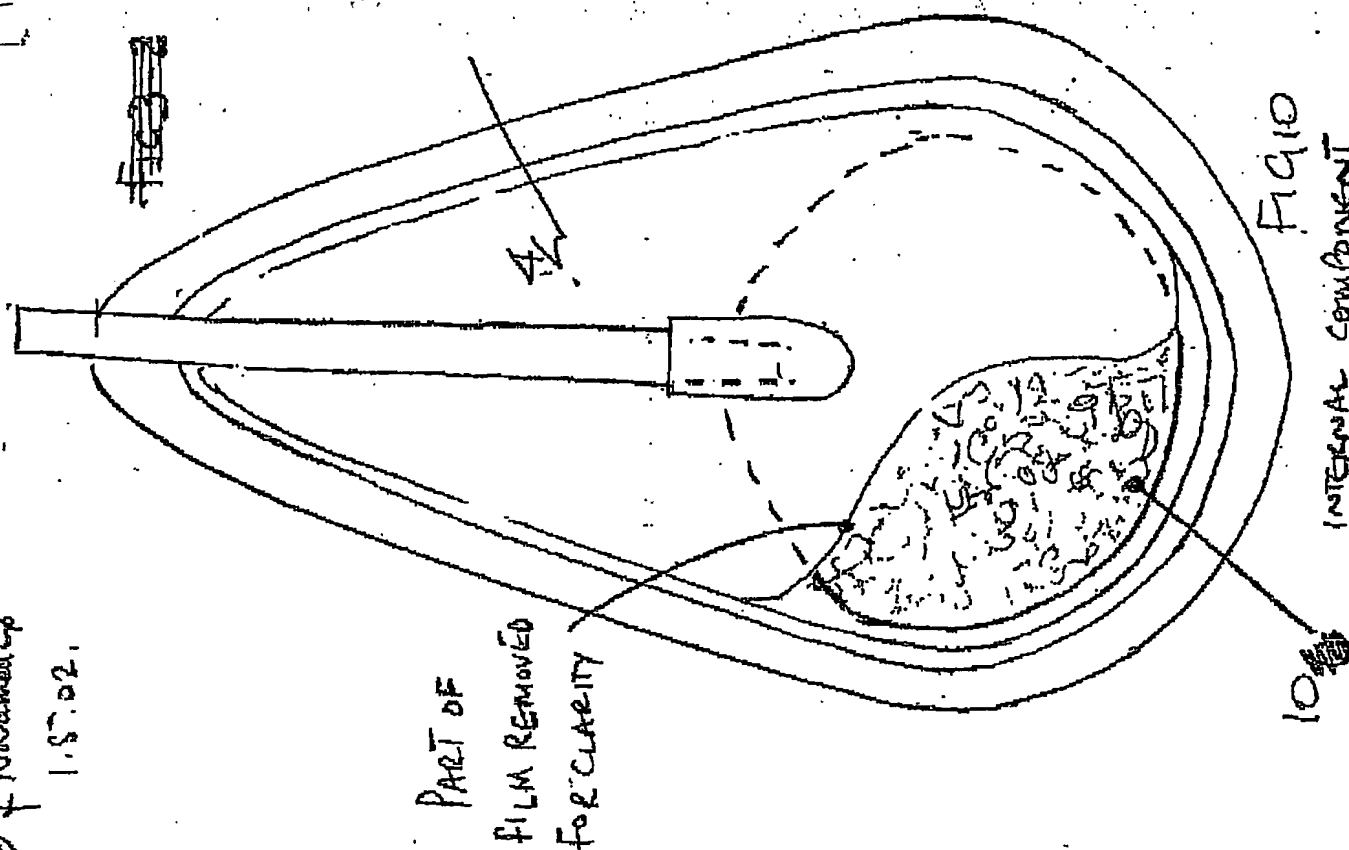
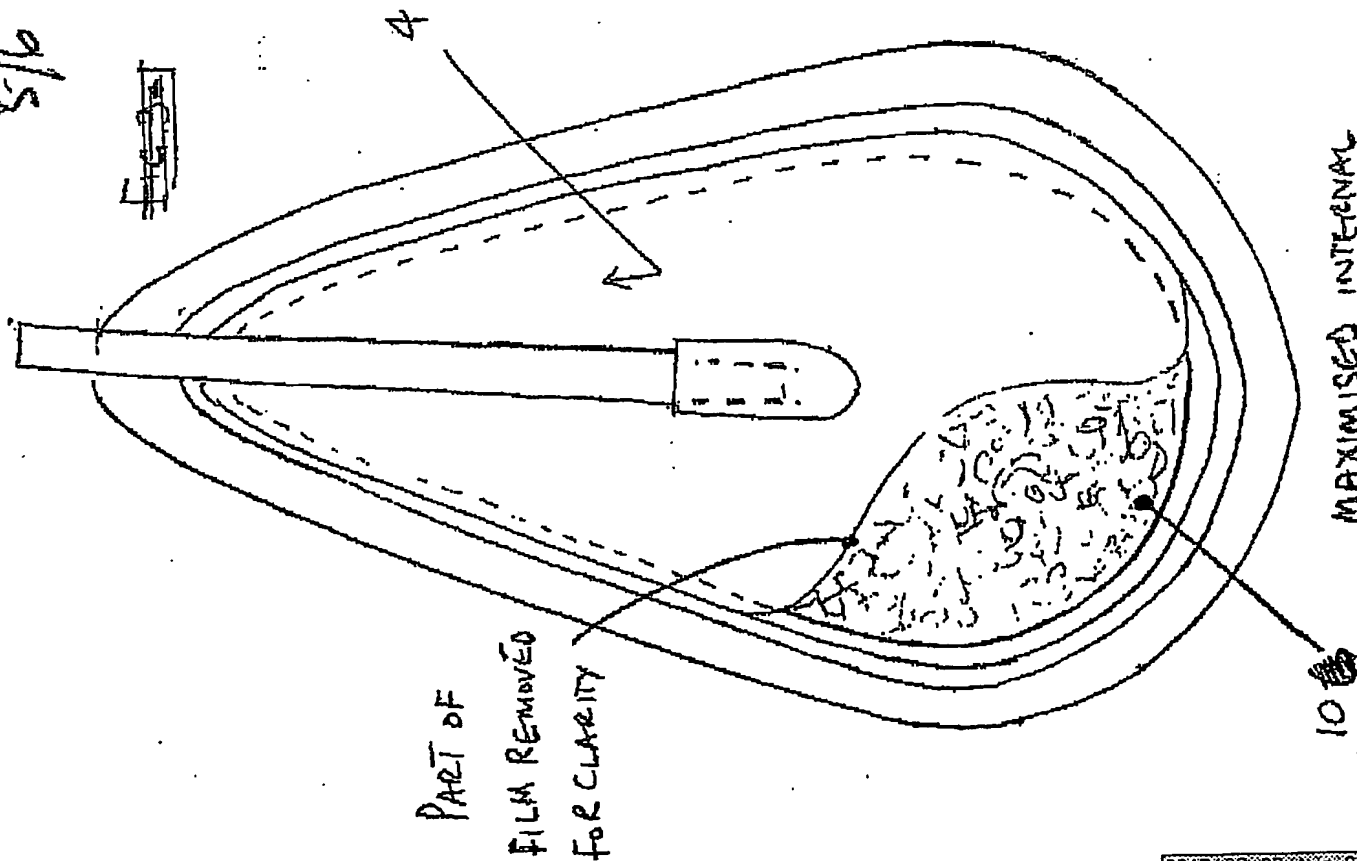
FIG 1B

2 of Noramexix
W 1.5102

FRONT & SIDE ELEVATIONS
OF FOOT SHOWING
BLADDER & PART OF GARNETS

© f Novamed up
1.5.02.

5/6



**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.